K094044

MAR 23 2010

Tayside Flow Technologies Ltd.
Traditional 510(k)

For the Spiral Laminar Flow™ Vascular Arteriovenous Graft

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

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Date Prepared:

18th March 2010

Tayside Flow Technologies Ltd.
Traditional 510(k)
For the Spiral Laminar Flow™ Vascular Arteriovenous Graft
510(k) Summary

Device Classification Information:

Regulation Number	Device Name	Device Class	Product Code	Classification Panel
870.3450	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter	Class 2	DSY	Cardiovascular
870.3450	Prosthesis, Vascular Graft, Of Less Then 6mm Diameter	Class 2	DYF	Cardiovascular

Device Trade Name:

Spiral Laminar Flow™ Vascular Arteriovenous Graft

Device Common Name:

ePTFE Vascular Graft with SLF™

Intended Use:

The Spiral Laminar Flow™ Vascular Arteriovenous Graft is a vascular prosthesis, which is intended for use as a subcutaneous arteriovenous conduit for vascular access during hemodialysis.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Summary of Substantial Equivalence:

The Tayside Flow Technologies (TFT) Spiral Laminar Flow™ Vascular Arteriovenous Graft is substantially equivalent to TFT SLF™ Peripheral Vascular Graft (K083169), Veryan Medical Limited SwirlGraft™ Graft (K051312/K060741), Bard IMPRA Venaflo® Vascular Access Graft (K052282), Bard IMPRA CenterFlex® Vascular Access Graft (K924360) and Vascutek PTFE Supported ePTFE Vascular Prostheses (K043552).

Device Description:

The TFT Spiral Laminar Flow™ Vascular Arteriovenous Graft is to be used as an arteriovenous conduit for hemodialysis access. The graft has a specially designed section which is intended to induce spiral laminar flow.
This section is designed to propagate spiral flow though the graft and into the distal circulation. TFT Spiral Laminar Flow™ Vascular Arteriovenous Graft is manufactured from a straight tubular expanded polytetrafluoroethylene (ePTFE) vascular graft. The straight graft is combined with TFT's unique SLF™ external spiral flow inducer and inducer indicator, both made from ChronoFlex® C-80A; a Biodurable Medical Grade polyurethane.

The inducer indicator is a palpable ring over the proximal end of the spiral flow inducer. Its purpose is to indicate to the user where the spiral inducer segment begins since it is intended that cannulation in this segment should be avoided.

Technological Characteristics:

A comparative review of the TFT Spiral Laminar Flow™ Vascular Arteriovenous Graft with the predicate devices found that the technological characteristics, performance and principle of operation were substantially equivalent.

A comparison is presented in the table below:

Property	**New Device:** **TFT SLF™ Vascular Arteriovenous Graft**	**TFT SLF™ Vascular Peripheral Graft**	**Veryan Medical SwirlGraft™ Vascular Access Graft**	**Bard Venaflo Vascular Access Graft**	**Bard IMPRA CenterFlex Vascular Access Graft**	**Vascutek Arteriovenous Graft**
Device Manufacturer	Tayside Flow Technologies Ltd	Tayside Flow Technologies Ltd	Veryan Medical Ltd.	Bard IMPRA	Bard IMPRA	Vascutek Ltd.
Device Trade Name	Spiral Laminar Flow ™ Vascular Arteriovenous Graft	Spiral Laminar Flow ™ Vascular Peripheral Graft	SwirlGraft™ Vascular Access Graft	Venaflo ™ II Vascular Graft	IMPRA CenterFlex Grafts	Maxiflo With PTFE Support Seal PTFE with PTFE Support
510(K) Number	N/A	K083169	K051312/ K060741	K052282	K924360	K043552
Device Common Name	ePTFE Vascular Graft with SLF™	ePTFE Vascular Graft with SLF™	ePTFE Vascular Graft	ePTFE Vascular Graft Prosthesis	ePTFE Vascular Graft Prosthesis	ePTFE Vascular Graft Prosthesis
Device Classification name	Prosthesis, Vascular Graft, Of 6mm and Greater Diameter and Prosthesis, Vascular Graft, Of Less Then 6mm Diameter	Prosthesis, Vascular Graft, Of 6mm and Greater Diameter and Prosthesis, Vascular Graft, Of Less Then 6mm Diameter	Prosthesis, Vascular Graft, Of 6mm and Greater Diameter	Prosthesis, Vascular Graft, Of 6mm and Greater Diameter	Prosthesis, Vascular Graft, Of 6mm and Greater Diameter	Prosthesis, Vascular Graft, Of 6mm and Greater Diameter
Device Classification	Class II	Class II	Class II	Class II	Class II	Class II
Materials	ePTFE and PU	ePTFE, PTFE and PU	ePTFE	ePTFE and PTFE	ePTFE and PTFE	ePTFE and PTFE
Tube	External spiral inducer 6cm long at the distal end of tube	External spiral inducer 10cm long at the distal end of tube	Small amplitude helical geometry along the tube length	Straight tube distal end diameter radially expanded	Straight tube	Straight tube
Beading	No	Yes	No	Partial beading optional	Partial beading optional	Yes
Distal End Modification	Yes	Yes	No	Yes	No	No
Diameter	5, 6 and 7mm	5, 6, 7 and 8mm	6mm	6, 7 and 8mm	6, 7 and 8mm	6, 7 8 and 10 mm
Intended Use	Subcutaneous arteriovenous	Bypass or reconstruction	Subcutaneous arteriovenous	Subcutaneous arteriovenous	Subcutaneous arteriovenous	Creation of subcutaneous

Property	New Device: TFT SLF™ Vascular Arteriovenous Graft	TFT SLF™ Vascular Peripheral Graft	Veryan Medical SwirlGraft™ Vascular Access Graft	Bard Venaflo Vascular Access Graft	Bard IMPRA CenterFlex Vascular Access Graft	Vascutek Arteriovenous Graft
	conduits for hemodialysis access	of occluded or diseased peripheral arterial blood vessels.	conduit for vascular access.	conduits for blood access only	conduits for blood access only	arteriovenous conduits for blood access, bypass or reconstruction of occluded or diseased arterial blood vessels
Intended Location of Use	Forearm, upper arm, thigh	Either above or below the knee	Forearm, upper arm, thigh	Forearm, upper arm, thigh	Forearm, upper arm, thigh	Forearm, upper arm, thigh, below knee
Device Description	An ePTFE graft with a pre-trimmed cuff and unique SLF™ external spiral flow inducer and inducer indicator made from Medical Grade polyurethane (PU) at the distal end.	An ePTFE supported graft with a pre-trimmed cuff and and unique SLF™ external spiral made from Medical Grade polyurethane (PU) at the distal end.	A 6mm expanded ePTFE vascular graft that is manufactured with a small amplitude helical geometry along its entire length. The Swirl Graft Vascular Access Graft is a standard wall ePTFE construction with no external support.	An expanded ePTFE vascular graft with a radially expanded pre-formed venous cuff at the distal end. The grafts are available in various lengths and diameters, in straight, stepped and tapered configurations, with and without external support and with or without a carbon lining	An expanded ePTFE vascular graft The grafts are available in various lengths and diameters, in straight, tapered and stepped configurations, with and without external support and with or without a carbon lining	A supported or unsupported ePTFE vascular graft

Performance Data:

Bench testing and animal data demonstrated that the safety and effectiveness of the TFT Spiral Laminar Flow™ Vascular Arteriovenous Graft is equivalent to the predicate devices.

- **Biocompatibility Testing**

  Tayside Flow Technologies (TFT) Spiral Laminar Flow™ Vascular Arteriovenous Graft is a straight tubular vascular graft made from expanded polytetrafluoroethylene (ePTFE). The unique SLF™ spiral flow inducer and inducer indicator are injection molded onto the outer surface of the straight graft. The inducer and indicator are made from ChronoFlex® C-80A; a Biodurable Medical Grade polyurethane, further information is available in as section 11.

  To determine the biocompatibility testing required for the TFT graft materials the following was taken into account:

- The requirements of ISO 10993 Part1 and especially Annex A of this part which provides guidance on the selection of tests

- The fact that the materials used in the TFT graft are already well-characterised and are approved for use as long-term vascular implants. Section 11 includes a list of vascular devices which make use of these materials and which are 510(k) cleared.

Based on this analysis it was determined that the tests specified in the following parts of ISO 10993 were appropriate: parts 4, 5, 6, 10, 11 and 13.

These tests performed in compliance with GLP, confirmed that the biocompatibility of the Spiral Laminar Flow™ Vascular Arteriovenous Graft is sufficient for their intended use.

These test results are further supported by the fact that these materials have been in clinical use in implant applications for many years with good results.

Further proof of the biocompatibility of the materials used in the TFT graft was provided by the fact that both the materials used have been cleared by FDA for vascular graft use as already mentioned. The details of the 510(k)s are given in section 11.

- **Performance Testing**

The determination of the optimum configuration for the profile of the TFT graft was based on 1) a literature review, 2) computational fluid dynamics (CFD) and 3) flow rig work. A number of design areas were evaluated:

1. Clinical Literature Review (Appendix B)
2. Helical angle (computational fluid dynamics and flow rig)
3. Number of ridges (computational fluid dynamics and flow rig)
4. Height of ridge (computational fluid dynamics and flow rig)
5. Ridge profile (computational fluid dynamics and flow rig)
6. Graft profile in polyester (flow rig)

Good correlation of CFD data, flow rig data and *in vivo* data confirmed the suitability of the design.

Haemodynamic Testing: Effect of Diameter

As 6mm and 8mm grafts are commercially available for infrainguinal bypass, there is no 'industry standard' as far as diameter is concerned. However, 6mm through 8mm grafts are commonly used for arteriovenous access. To verify that 6mm and 8mm grafts have comparable blood flow characteristics, in-house flow rig and computational fluid dynamic work has been carried out.

Physical Testing

Characterisation and Physical testing has been carried out to ISO7198 Cardiovascular implants - tubular vascular prosthesis. This includes:-

- Water permeability
- Circumferential tensile strength

- Longitudinal tensile strength
- Probe burst strength
- Usable length of formed material
- Relaxed internal diameter
- Wall thickness
- Pressurised internal diameter
- Suture retention strength
- Kink diameter / radius
- Dynamic compliance

The test results demonstrate that the TFT Spiral Laminar Flow™ Vascular Arteriovenous Graft has sufficient strength and physical properties to perform as intended under the expected *in vivo* loading conditions.

Animal Testing

Development of SLF grafts

TFT has completed the following animal studies during the development of the TFT Spiral Laminar Flow™ ePTFE Vascular Grafts.

STUDY	Length of Recovery Study	Species Used	Description	Number In Each Group	Purpose
HSAW (100)	6 Months	Mini-Pig	Bard Control vs. Bard+TFT Spiral POLYESTER 8 mm	8	Blood flow Model Development
HSAW (103)	1 Week	Mini-Pig	Bard Control vs. Bard+TFT Spiral POLYESTER 8 mm	1	
HSAW (104)	1Months	Mini-Pig	Bard Control vs. Bard+TFT Spiral vs. TFT (McMurry) POLYESTER 8 mm	2	
NPIMR (pilot)	1 Month	Sheep	TFT (McMurry) POLYESTER 8 mm	1	
NPIMR (SH-02)	3 Month	Sheep	Bard Control vs. Bard+TFT Spiral POLYESTER 8 mm	5	
CHUM (TFT-CHUM pilot) TFT-8-004	2 Weeks	Dog	Model Development Bard Control vs. TFT (McMurry) POLYESTER 8 mm	2	Blood flow Model Development AND Safety Study Development
CHUM (TFT-8-005)	6 Weeks	Dog	Bard Control vs. TFT (McMurry) POLYESTER 8 mm	2	
CHUM and MHI (TFT-8-006)	20 Weeks	Dog	Bard Control vs. TFT (McMurry) POLYESTER 8 mm	10	Safety Study/ Proof of principle and Performance
TFT-8-007	14 Weeks	Sheep	BARD ePTFE 8mm	2	Proof of principle study

STUDY	Length of Recovery Study	Species Used	Description	Number In Each Group	Purpose
NPIMR (SH03)	2 Weeks	Sheep	4 mm Polyester Spiral Grafts	4	Proof of principle study (Performance Study 4 mm Vascular Grafts)
G0003-09	2 Weeks	Pig	6mm ePTFE Spiral Access Grafts v 6mm ePTFE Control Access Grafts	2	Proof of principle study (Performance Study 6 mm Vascular Grafts)

Safety and Effectiveness:

The TFT SLF™ Vascular Arteriovenous Graft utilises similar technology currently found in legally marketed predicate devices. Based on testing and comparison with the predicate devices, the TFT SLF™ Vascular Arteriovenous Graft indicated no adverse indications or results. It is our determination that the TFT Spiral Laminar Flow™ Vascular Arteriovenous Graft is safe, effective and performs within its design specifications and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 3 2010

Tayside Flow Technologies LTD
c/o Mr. Rudy Mounia
1141 E. Hawken Way
Chandler, AZ 85286

Re: K094044
Trade Name: Spiral Laminar Flow™ Vascular Arteriovenous Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: II (two)
Product Code: DSY
Dated: December 28, 2009
Received: December 31, 2009

Dear Mr. Mounia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094044

Device Name: Spiral Laminar Flow™ Vascular Arteriovenous Graft

Indications for Use:

The Spiral Laminar Flow™ Vascular Arteriovenous Graft is a vascular prosthesis, which is intended for use as a subcutaneous arteriovenous conduit for vascular access during hemodialysis.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Prescription Use ___X____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _______
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K094044